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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,827	01/15/2004	Michael R. Rosen	68262-A/JPW/PJP/NS	5518

7590 09/21/2005

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EXAMINER	
SINGH, ANOOP KUMAR	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,827	ROSEN ET AL.	
	Examiner	Art Unit	
	Anoop K. Singh	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-64 are pending

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 22, 39-48, and 63-64, drawn to composition of delivery of a gene to a syncytial structure comprising genetically modified stem cells with gene encoding MiRP1, classified in class 424, subclass 93.1.

II. Claims 1, 4-19 and 39-48 and 63-64, drawn to composition for delivery of a gene to a syncytial structure comprising genetically modified stem cells with gene encoding HCN or modified HCN channels, classified in class 424, subclass 93.1.

III. Claims 20-22, 49-50 and 64, drawn to composition for ion channel transfer comprising genetically modified stem cell with gene encoding MiRP1 and treated with a compound that creates ion channel, classified in class 514, subclass 2.

IV. Claims 20, 23-38, 49-50 and 64, drawn to composition for ion channel transfer comprising genetically modified stem cell with gene encoding HCN or modified HCN channels and treated with a compound that creates ion channel, classified in class 514, subclass 2.

V. Claims 51-62, drawn to a method of treating cardiac condition using composition for ion channel transfer comprising genetically modified stem cell with gene encoding MiRP1 and treated with a compound and creates ion channel, classified in class 514, subclass 2.

VI. Claims 51-62, drawn to a method of treating cardiac condition using composition for ion channel transfer comprising genetically modified stem cell with gene encoding HCN or modified HCN channels and treated with a compound that creates ion channel, classified in class 514, subclass 2.

The Inventions of groups I-II are patentably distinct each from other because they are drawn to compositions that have distinct structure, function, and mode of utilities. For example, the invention of group I require stem cells modified by gene encoding MiRP1, while invention of group II require HCN or HCN channel related genes. The genes of groups I and II have distinct sequence and require different searches as each sequence has a distinct structure and encodes different protein that would have different biological effect. Thus, searching for compositions used in groups I-II will not be coextensive in the patent and non-patent literature.

The Inventions of groups III-IV are patentably distinct each from other because they are drawn to compositions that have distinct structure, function, and mode of utilities. For example, the invention of group III require stem cells with MiRP1 and a non nucleic acid compound, while invention of group IV require stem cell with HCN channel family of genes and a compound. They have distinct sequence and require different searches as each sequence has a distinct structure and encodes different protein. Furthermore, the interaction and effects of non-nucleic compound with MiRP1 will be different and distinct as compare to HCN or HCN related genes. Searches for compositions used in treatment method will not be coextensive in the patent and non-patent literature

The inventions of groups I-II and III-IV are patentably distinct each from other because they are drawn to compositions that have distinct structure, function and utility. The inventions of groups I-II require only genetically modified stem cells in syncytial structure, while group III-IV require treatment of genetically modified stem cells with non nucleic acid compound to create ion channel. The genetically modified stem cells have different mode of action, function or effect as compared to cells treated with a non nucleic acid compound like a peptide or chemical compound. The nucleic acid require expression vector for the delivery to stem cells while chemical compounds are active compounds and act directly upon treatment. Therefore, searching for distinct compositions in a single patent application would constitute an undue burden on the examiner because of non-coextensive nature of these searches.

The inventions of groups V-VI are patentably distinct, each from other because they are drawn to methods that have distinct mode of action, require separate composition for practice and produce different results. For example, treatment of a non nucleic acid compound with stem cell modified with MiRP1 gene will elicit different pharmacological response as compare to cells modified with HCN or HCN related genes as claimed for invention of group VI. Thus, compositions of method of groups V and VI will not be coextensive in patent and non-patent literature.

The compositions of the groups I-IV are patentably distinct each from the methods of groups V-VI because methods cannot be used to produce the compositions. Alternatively, the compositions may not be used in methods or will be used in more than one method.

Therefore, the inventions of groups I-VI are patentably distinct each from other and will require separate and non-coextensive searches in the patent and non-patent literature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

Claims 1, 4, 8, 12, 16, 20, 23, 27, 31, 35 recite plurality of disclosed patentably distinct sequences: HCN1, HCN2, HCN4, E324 A-HCN2, Y331A-HCN2, Y331A and E324A-HCN2. Each of these sequence has a distinct structure, encodes different protein that would have different function and therefore Applicant is required to elect one sequence, even though this requirement is traversed. It is noted that this is a restriction requirement, not election of species.

Claims 41-48 generic to a plurality of disclosed patentably distinct species comprising heart, bladder, an artery, an arteriole, a liver, gastrointestinal tract, tumor from epithelial tissue and tumor originating from smooth muscle cells.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 57-62 generic to a plurality of disclosed patentably distinct species comprising inducing current in heart, increasing heart rate, inducing current in the cell, contraction of the cell, shortening the time required to activate cells and changing the membrane potential of the cell.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed invention: pacemaker current and cardiac rhythm disorder.
Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 51 is generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: conduction block, complete atrioventricular block, incomplete artioventricular block and sinus node dysfunction.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 54 is generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: topical application, microinjection and catheterization.
Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 55 is generic.

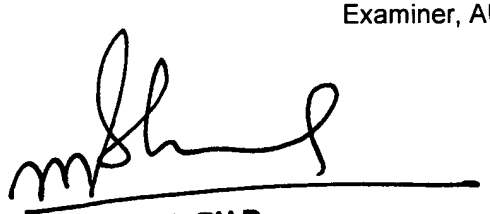
Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272- 0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anoop Singh
Examiner, AU 1632



RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER